510(k) Summary

K081877

1. COMPANY NAME AND ADDRESS

JAN - 5 2009

Dutch Ophthalmic Research Center International bv
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

Contact : Mr. Ger Vijfvinkel, President
Phone : +31 181 458080
Fax : +31 181 458090
Date of summary : September 10, 2008

2. DEVICE NAME

Trade Name : ASSOCIATE
Common Name : Phacoemulsification/vitrectomy System
Classification Name : Phacofragmentation system (21 CFR 886.4670, Product Code HQC, HQE)

3. PREDICATE DEVICES

510(k)	Clearance Date	Device Description
K063331	12/19/2006	Bausch & Lomb™ NGX Microsurgical System (Marketed as the Bausch & Lomb Stellaris)
K060366	4/7/2006	AMO Ophthalmic Surgical System (Marketed as the AMO Signature)
K021564	7/2/2002	Alcon Infiniti™ Cataract Extraction System
K961310	6/27/1996	Storz Premiere II Microsurgical System (Marketed as the Bausch & Lomb™ Millennium Microsurgical System)
K952213	8/9/1995	Alcon System 20000™ Legacy® Microsurgical System (Also marketed as the Alcon Accurus Ophthalmic Systems)

4. DEVICE DESCRIPTION

The Associate is medical electrical equipment to be used during eye surgery. The Associate is intended for ophthalmic anterior and posterior segment surgery.

It provides capabilities for phacoemulsification, phacofragmentation, diathermy coagulation, irrigation/ aspiration, vitrectomy, illumination, air/fluid exchange, silicone oil injection and extraction. The equipment has a display with touch screen for selecting and activating the functions. With the equipment a footswitch and a remote control are delivered for control by the surgeon. The equipment can be installed on a trolley and is able to control an automated infusion pole.

5. INTENDED USE

The ASSOCIATE is intended for ophthalmic anterior and posterior segment surgery. It provides capabilities for phacoemulsification, phacofragmentation, diathermy coagulation, irrigation/ aspiration, vitrectomy, illumination, air/fluid exchange, silicone oil injection and extraction.

6. SUMMARY OF NON-CLINICAL TESTS

Prior to commercialization, safety tests of the ASSOCIATE have demonstrated compliance with applicable requirements of the following standards and the test reports have been filed as quality records for future review as required under 21CFR820.180.

Standards	Standards Title
IEC 60601-1:1988, A1:1991, A2:1995	Medical electrical equipment Part 1: General requirements for safety.
IEC 60601-1-2:2001, A1:2006	Medical electrical equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.
IEC 60601-1-4:1996, A1:1999	Medical electrical equipment Part 1: General requirements for safety; 4. Collateral Standard: Programmable electrical medical systems.
IEC 60601-2-2:1998	Medical electrical equipment Part 2-2: Particular requirements for the safety of high frequency surgical equipment.
ISO 14971:2000, A1:2003	Medical devices – Application of Risk Management to Medical Devices
ISO 11607-1:2006	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.
ISO 11135-1:2007	Sterilization of health care products – Ethylene oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dutch Ophthalmic Research Center International BV
c/o Ger Vijfvinkel, President
Scheijdelveweg 2
Zuidland, NL-3214 VN
The Netherlands

JAN - 5 2009

Re: K081877
Trade/Device Name: Associate 2500 Dual and Compact Systems
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: December 19, 2008
Received: December 23, 2008

Dear Mr. Vijfvinkel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081877

Device Name: ASSOCIATE

Indications For Use:

The ASSOCIATE is intended for ophthalmic anterior and posterior segment surgery. It provides capabilities for phacoemulsification, phacofragmentation, diathermy coagulation, irrigation/aspiration, vitrectomy, illumination, air/fluid exchange and silicone oil injection & extraction.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K081877